APR 2 6 2002

K020705 page 1 of 2

SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary in formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

New Device Name:	**SiiS#1 Tissue Suspension System**
Predicate Device Name:	**Tension Free Vaginal Tape (TVT) System**

Device Description

The SiiS#1 Tissue Suspension Device is a sterile single use device, consisting of one piece of undyed polyester tubular mesh approximately 6 mm diameter x 305 mm long (.250 x 12 inches) with both ends terminating in toggle type tissue anchors. The anchors and part of the mesh are held within a long needle inserter. Attached to the mesh creating a secondary sling is a sliding mesh approximately 80 mm long connected to the longer mesh with sliding locks. The sliding locks are advanced with the sling locator to shorten the length of the sling until desired length is achieved. Polyester tubular mesh is constructed of knitted filaments of extruded polyester strands identical in composition to that used in polyester non-absorbable surgical suture. The material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

The SiiS#1 Inserter is provided sterile and single use. The inserter is made of stainless steel with an anodized aluminum handle. The tip of the inserter is constructed to accept the toggle anchors and part of the tubular mesh. The inserter is intended to facilitate the passage of the toggle anchors through the rectus fascia below the abdominal skin.

The SiiS#1 Reusable Sling Locator is provided sterile and single use. The locator is made of polyacetal or equivalent and is intended to facilitate the position of the sliding sling on the longer suspender. It is connected and fixed to the longer suspender and interfaces with the sliding sling adjustment locks.

Intended Use

The SiiS#1 Device is intended to be used as a pubourethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Indications Statement

Indications (from labeling): The SiiS#1 device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The SiiS#1 Inserter, Sling Locater and Urethral Probe are available and intended to facilitate placement of the SiiS#1 device.

Technological Characteristics

Technologically both the new device and predicate device are the same (i.e., both are meshes that provide pubourethral support). Additionally, both devices utilize accessories for use in the surgical procedure. Any differences between the devices do not raise new questions of safety and effectiveness.

Performance Data	Cadaver testing has shown that the SiiS#1 has a pull-out force that is well over that of the predicate device. Cadaver test data is provided in Attachment # 5.
Conclusions	Based on the 510(k) summaries and the 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.
Contact	Dan Moor, Chief Engineer, T..A.G. Medical Products LTD, Kibbutz Gaaton 25130, Israel
Date	02/01/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2002

Mr. Dan Moor
Chief Engineer
T.A.G. Medical Products LTD
Kibbuts Gaaton
Israel 25130

Re: K020705
Trade/Device Name: SiiS#1 Tissue Suspension System
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: February 4, 2002
Received: March 4, 2002

Dear Mr. Moor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020705

Device Name: SiiS#1 Tissue Suspension System

Indications for Use:

The SiiS#1 Bladder-Neck Suspension Device is a sterile, single-use device intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting form urethral hypermobility and/or intrinsic sphincter deficiency. The SiiS#1 Bladder-Neck Suspension Device Inserter, and Sling Locator are provided and are intended to facilitate the placement of the SiiS#1 Bladder-Neck Suspension Device.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The- Counter Use_____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020705

(Optional Format 1-2-96)